



Nano Risk governace and data management

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<http://www.bionanoteam.com/>

Ljubljana, 6.2.2020, Nanotechnology and nanoApplication





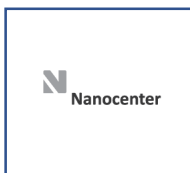
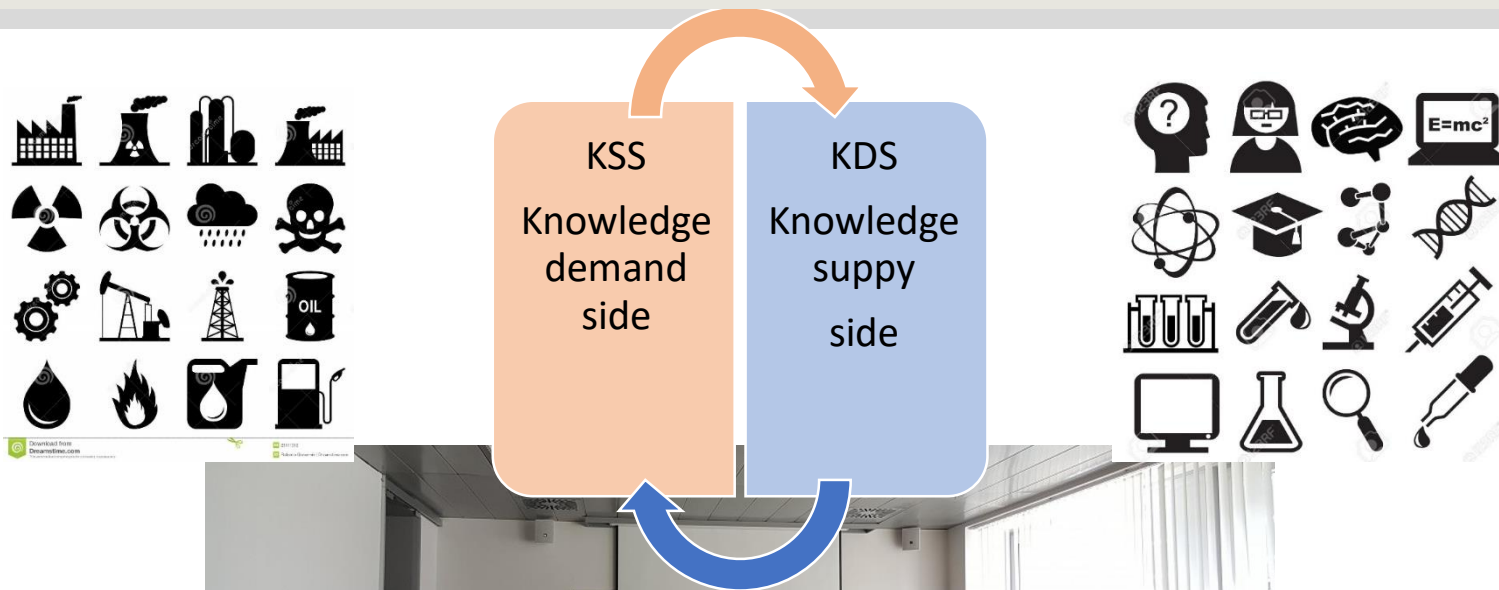
SIS EGIZ

**Slovensko
Inovacijsko
Stičišče**

Evropsko
Gospodarsko
Interesno
Združenje

Ustanovitvena okrogla miza Slovenske nanotehnoške platforme

Torek, 13. 6. 2017 ob 15.30 na UL Fakulteti za kemijo in kemijsko tehnologijo



University of Ljubljana, Biotechnical Faculty, Research group for nanobiology and nanotoxicology

- EU FP7 NanoValid (2011-2015)
- EU FP7 NanoMILE (2013-2017)
- H2020, RIA NanoFASE (2015-2019)
- H2020, MSCA-ITN-2015 Pandora (2016-2019)
- H2020, NANORIGO (2019-2023)
- DaNa 2.0, funded by German Federal Ministry of Education and Research (ongoing)

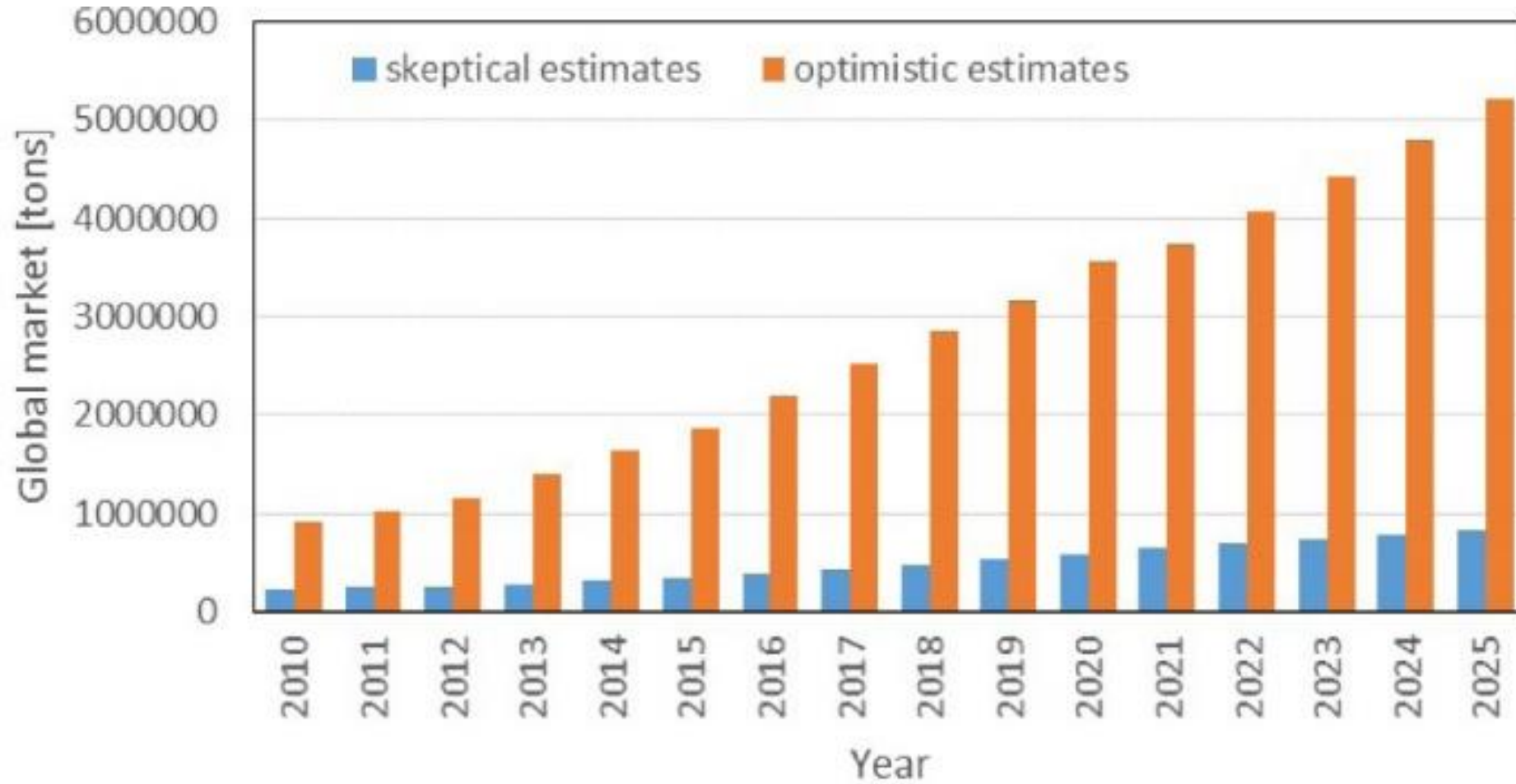
❖ NanoSafetyCluster

National centres of excellence (CO):

- CO NAMASTE
- CO Nanocenter



Nanotechnologies



Safety

Safety Projects

- [NanoSafety Cluster](#)
- [NanoValid](#)
- [NanoImpactNet](#)
- [SIINN - Safe Implementation](#)
- [NHECD](#)
- [Safenano](#)
- [Marina FP7](#)
- [NANOCODE](#)
- [NANOSH](#)
- [nanoSTAIR](#)
- [Steptoe & Johnson](#)
- [Legal/Regulatory Issues](#)
(nanotech.lawbc.com)
- [DaNa](#)
- [NANOTRANSPORT](#)
- [EURO-NanoTox](#)
- [BioNanoNet](#)
- [NANoREG](#)
- [NanoSafePack](#)
- [Nanomicex](#)
- [eNanoMapper](#)

Working Groups

Promoting NanoSafety Research

***NanoSafety
Cluster***



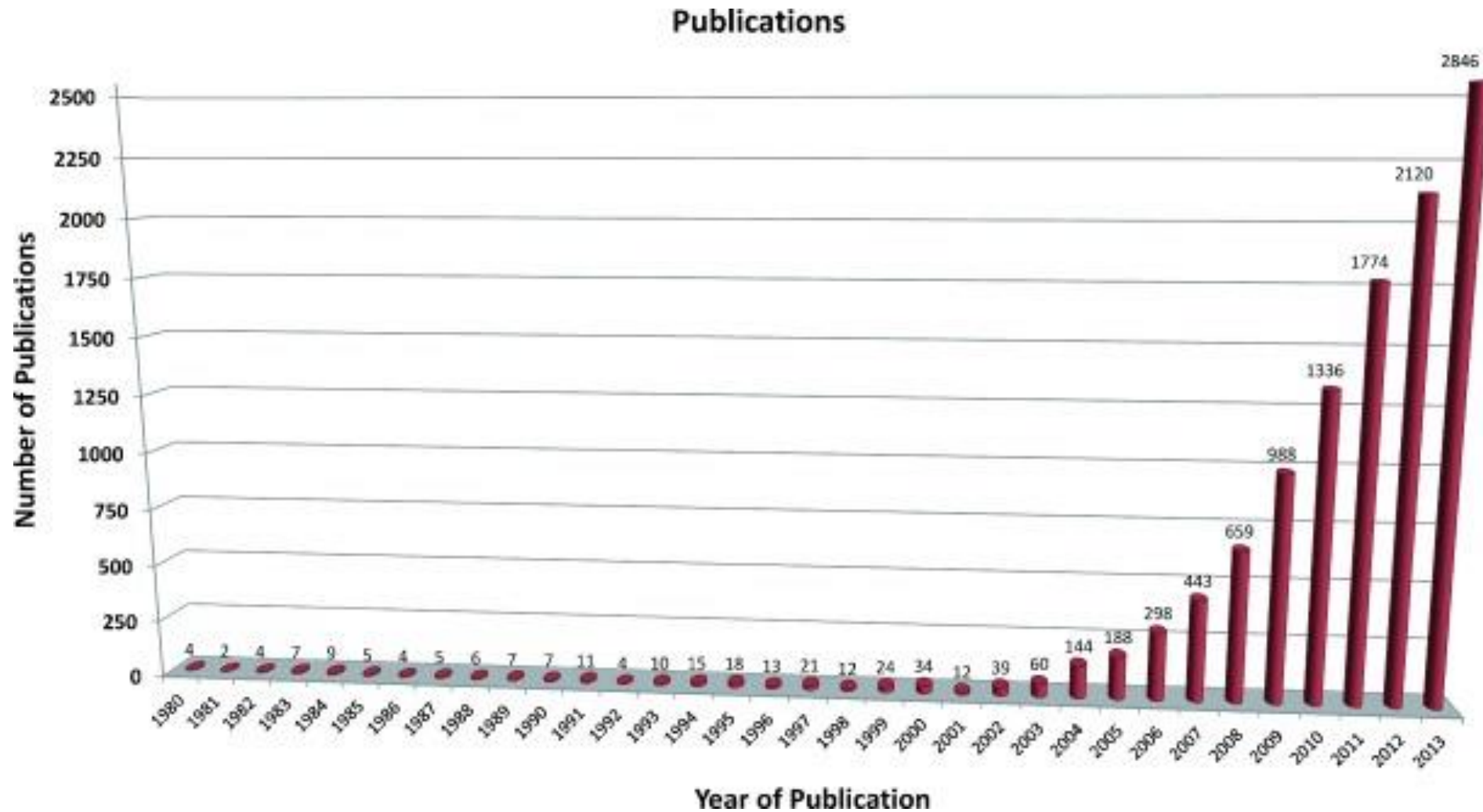
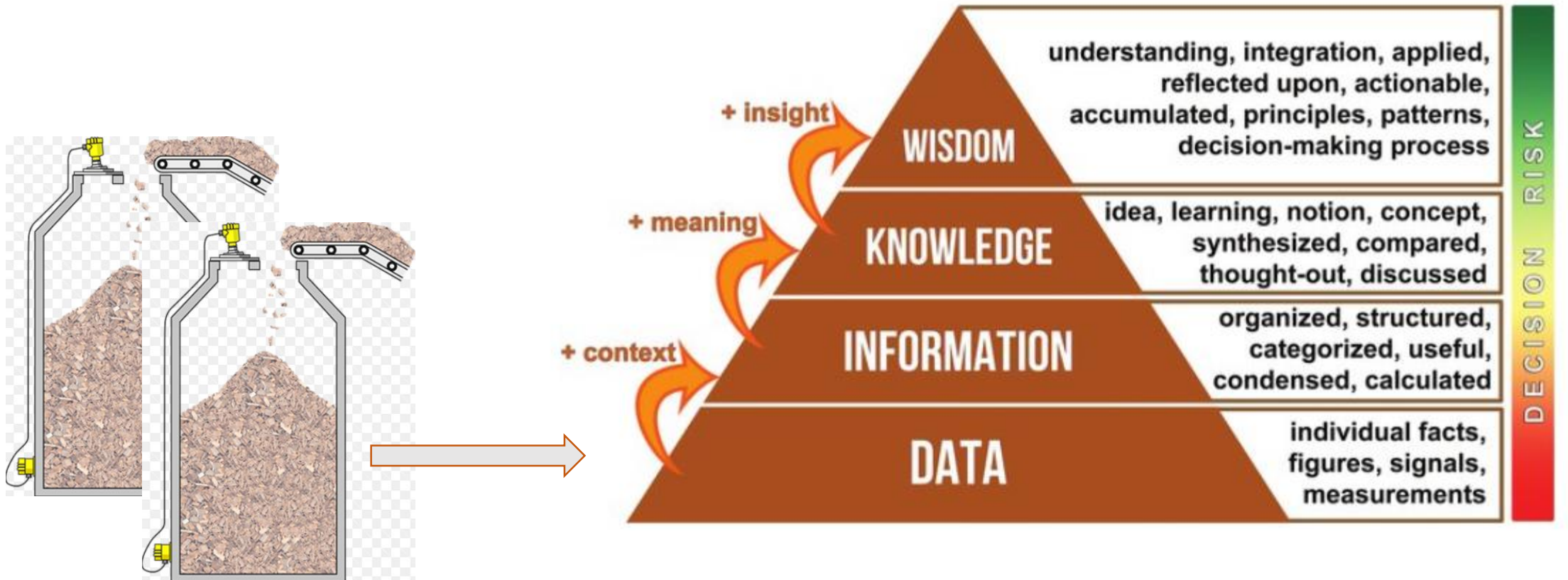


Figure 1: The number of published papers on nanotoxicology from 1980 to 2013.

https://www.researchgate.net/publication/266746424_Nanosafety_Research-We_on_the_Right_Track/figures?lo=1

Data



Examples of data bases

- [Composite Table RML November 2019 HQ1 PDF \(77 pp, 7.62 MB\)](#)

Regional

Key: I = IRIS; P = PPRTV; O = OPP; A = ATSDR; C = Cal EPA; X = PPRTV Screening Level; H = HEAST; W = TEF applied; E = RPF applied; G = user's guide Section 5; M = mutagen; V = volatile; R = RBA applied; c = cancer; n = noncancer; * = where n SL < 100X c SL; ** = where n SL < 10X c SL; SSL values are based on DAF=1; m = ceiling limit exceeded; s = Csat exceeded.

Toxicity and Chemical-specific Information											Contaminant		Removal Levels												
SFO (mg/kg-day) ¹	Key	IUR (ug/m ³) ¹	Key	RfD _o (mg/kg-day)	Key	RfC ₁ (mg/m ³)	Key	Vol I	Mutagen	GIASS	ABS ₂	C ₁₀₀ (mg/kg)	Analyte	CAS No.	Resident Soil (mg/kg)	Key	Industrial Soil (mg/kg)	Key	Resident Air (ug/m ³)	Key	Industrial Air (ug/m ³)	Key	Tapwater (ug/L)	Key	MCL (ug/L)
2.20E+02	I	6.20E-02	I					V				4.22E+03	Bis(chloromethyl)ether	542-88-1	8.30E-03	c	3.60E-02	c	4.50E-03	c	2.00E-02	c	7.20E-03	c	
				5.00E-02	I							0.1	Bisphenol A	80-05-7	3.20E+03	n	4.10E+04	n					7.70E+02	n	
				2.00E+00	P	2.00E-02	P	V					Boron And Borates Only	7440-42-8	1.60E+04	n	2.30E+05	nm	2.10E+01	n	8.80E+01	n	4.00E+03	n	
				2.00E+00	P	2.00E-02	P	V					Boron Trichloride	10294-34-5	1.60E+05	nm	2.30E+06	nm	2.10E+01	n	8.80E+01	n	4.20E+01	n	
7.00E-01	I			4.00E-02	C	1.30E-02	C	V					Boron Trifluoride	7637-07-2	3.10E+03	n	4.70E+04	n	1.40E+01	n	5.70E+01	n	2.60E+01	n	
2.00E+00	X	6.00E-04	X	4.00E-03	I								Bromate	15541-45-4	9.90E+01	c**	4.70E+02	c*					1.10E+01	c**	1.00E+01
								V				2.38E+03	Bromo-2-chloroethane, 1-	107-04-0	2.60E+00	c	1.10E+01	c	4.70E-01	c	2.00E+00	c	7.40E-01	c	
				3.00E-04	X			V				8.96E+02	Bromo-3-fluorobenzene, 1-	1073-06-9	2.30E+01	n	3.50E+02	n					4.90E+00	n	
				3.00E-04	X			V				3.23E+02	Bromo-4-fluorobenzene, 1-	460-00-4	2.30E+01	n	3.50E+02	ns					4.60E+00	n	
											0.1		Bromoacetic acid	79-08-3											6.0E+01(G)
				8.00E-03	I	6.00E-02	I	V				6.79E+02	Bromobenzene	108-86-1	2.90E+02	n	1.80E+03	ns	6.30E+01	n	2.60E+02	n	6.20E+01	n	
6.20E-02	I	3.70E-05	C	2.00E-02	I	4.00E-02	X	V				4.04E+03	Bromochloromethane	74-97-5	1.50E+02	n	6.30E+02	n	4.20E+01	n	1.80E+02	n	8.30E+01	n	
				2.00E-02	I			V				9.32E+02	Bromodichloromethane	75-27-4	2.90E+01	c*	1.30E+02	c	7.60E+00	c	3.30E+01	c	1.30E+01	c*	8.0E+01(G)
7.90E-03	I	1.10E-06	I	2.00E-02	I			V				9.15E+02	Bromoform	75-25-2	1.60E+03	ns	8.60E+03	c**s	2.60E+02	c	1.10E+03	c	3.30E+02	c**	8.0E+01(G)
				1.40E-03	I	5.00E-03	I	V				3.59E+03	Bromomethane	74-83-9	6.80E+00	n	3.00E+01	n	5.20E+00	n	2.20E+01	n	7.50E+00	n	
				5.00E-03	H			V					Bromophos	2104-96-3	3.90E+02	n	5.80E+03	n					3.50E+01	n	
1.00E-01	O			1.50E-02	O			A	V			9.66E+02	Bromopropane, 1-	106-94-5	2.20E+02	n	9.40E+02	n	1.00E+02	n	4.40E+02	n	2.10E+02	n	
1.00E-01	O			1.50E-02	O			V				0.1	Bromoxynil	1689-84-5	5.30E+02	c**	2.20E+03	c**					6.10E+01	c**	
6.00E-01	C	3.00E-05	I			2.00E-03	I	V				6.67E+02	Bromoxynil Octanoate	1689-99-2	6.70E+02	c**	3.20E+03	c**					2.40E+01	c**	
				3.00E-02	O			V				0.1	Butadiene, 1,3-	106-99-0	1.80E+00	n	7.60E+00	n	2.10E+00	n	8.80E+00	n	4.20E+00	n	
				1.00E-01	X			V				7.64E+03	Butanoic acid, 4-(2,4-dichlorophenoxy)-	94-82-6	1.90E+03	n	2.50E+04	n					4.50E+02	n	
				2.00E+00	P	3.00E+01	P	V				2.13E+04	Butanol, sec-	78-92-2	1.30E+05	nms	1.50E+06	nms	3.10E+04	n	1.30E+05	n	2.40E+04	n	
2.00E-04	C	5.70E-08	C	5.00E-02	I			V				0.1	Butylate	2008-41-5	3.90E+03	n	5.80E+04	n					4.60E+02	n	
3.60E-03	P			3.00E-01	P			V				0.1	Butylated hydroxyanisole	25013-16-5	2.70E+05	cm	1.10E+06	cm	4.90E+03	c	2.20E+04	c	1.50E+04	c	
				5.00E-02	P			V				1.08E+02	Butylated hydroxytoluene	128-37-0	1.50E+04	c**	6.40E+04	c**					3.40E+02	c**	
				1.00E-01	X			V				1.45E+02	Butylbenzene, n-	104-51-8	3.90E+03	ns	5.80E+04	ns					1.00E+03	n	
				1.00E-01	X			V				1.83E+02	Butylbenzene, sec-	135-98-8	7.80E+03	ns	1.20E+05	nms					2.00E+03	n	
				2.00E-02	A							0.1	Butylbenzene, tert-	98-06-6	7.80E+03	ns	1.20E+05	nms					6.90E+02	n	
				1.80E-03	I	1.00E-03	I	1.00E-05	A		0.025	0.001	Cacodylic Acid	75-60-5	1.30E+03	n	1.60E+04	n					4.00E+02	n	
				1.80E-03	I	5.00E-04	I	1.00E-05	A		0.05	0.001	Cadmium (Diet)	7440-43-9	7.10E+01	n	9.80E+02	n							5.00E+00
				5.00E-01	I	2.20E-03	C					0.1	Cadmium (Water)	7440-43-9				1.00E-02	n	4.40E-02	n	9.20E+00	n		
1.50E-01	C	4.30E-05	C	2.00E-03	I							0.1	Caprolactam	105-60-2	3.10E+04	n	4.00E+05	nm	2.30E+00	n	9.60E+00	n	9.90E+03	n	
2.30E-03	C	6.60E-07	C	1.30E-01	I							0.1	Captadol	2425-06-1	1.30E+02	n	1.50E+03	c**	6.50E+00	c	2.90E+01	c	3.20E+01	n	
				1.00E-01	I							0.1	Captan	133-06-2	8.20E+03	n	1.00E+05	c**	4.30E+02	c	1.90E+03	c	2.40E+03	n	
				5.00E-03	I							0.1	Carbaryl	63-25-2	6.30E+03	n	8.20E+04	n					1.80E+03	n	
				1.00E-01	I							0.1	Carbofuran	1563-66-2	3.20E+02	n	4.10E+03	n					9.40E+01	n	4.00E+01
7.00E-02	I	6.00E-06	I	4.00E-03	I	7.00E-01	I	V				7.38E+02	Carbon Disulfide	75-15-0	7.70E+02	ns	3.50E+03	ns	7.30E+02	n	3.10E+03	n	8.10E+02	n	
				1.00E-01	I	1.00E-01	I	V				4.58E+02	Carbon Tetrachloride	56-23-5	6.50E+01	c**	2.90E+02	c**	4.70E+01	c**	2.00E+02	c**	4.60E+01	c**	5.00E+00
				1.00E-01	P	1.00E-01	P	V				5.89E+03	Carbonyl Sulfide	463-58-1	6.70E+01	n	2.80E+02	n	1.00E+02	n	4.40E+02	n	2.10E+02	n	
				1.00E-02	I							0.1	Carboosulfan	55285-14-8	6.30E+02	n	8.20E+03	n					5.10E+01	n	
				1.00E-01	I							0.1	Carboxin	5234-68-4	6.30E+03	n	8.20E+04	n					1.90E+03	n	
						9.00E-04	I						Ceric oxide	1306-38-3	1.30E+06	nm	5.40E+06	nm	9.40E-01	n	3.90E+00	n			
				1.00E-01	I			V				0.1	Chloral Hydrate	302-17-0	7.80E+03	n	1.20E+05	nm					2.00E+03	n	
				1.50E-02	I							0.1	Chloramben	133-90-4	9.50E+02	n	1.20E+04	n					2.90E+02	n	
													Chloramines, Organic	E701235											4.0E+03(G)
4.00E-01	H											0.1	Chloranil	118-75-2	1.30E+02	c	5.70E+02	c					1.80E+01	c	
3.50E-01	I	1.00E-04	I	5.00E-04	I	7.00E-04	I	V				0.04	Chlordane	12789-03-6	3.50E+01	n	4.50E+02	n	7.30E-01	n	3.10E+00	n	7.40E-01	n	2.00E+00

Examples of data bases

<https://toxico.nibiohn.go.jp/english/datalist.html#vivo>

List of public data

Public (<i>in vivo</i>) data											To in vitro data
	Compound	Vehicle	Administration route	Organ	Single dose (mg/kg)			Repeat dose (mg/kg)			Remarks
					Low	Middle	High	Low	Middle	High	
1	acetaminophen	0.5% MC	Gavage	Liver / Kidney	300	600	1000	300	600	1000	
2	isoniazid	0.5% MC	Gavage	Liver	200	600	2000	50	100	200	
3	carbon tetrachloride	corn oil	Gavage	Liver	30	100	300	30	100	300	
4	phenobarbital	0.5% MC	Gavage	Liver	100	150	300	10	30	100	
5	valproic acid	0.5% MC	Gavage	Liver / Kidney	45	150	450	45	150	450	
6	clofibrate	corn oil	Gavage	Liver / Kidney	30	100	300	30	100	300	
7	rifampicin	0.5% MC	Gavage	Liver / Kidney	20	60	200	20	60	200	
8	naphthyl isothiocyanate	corn oil	Gavage	Liver	15	50	150	1.5	5	15	
9	allyl alcohol	corn oil	Gavage	Liver / Kidney	3	10	30	3	10	30	
10	phenylbutazone	0.5% MC	Gavage	Liver / Kidney	20	60	200	20	60	200	
11	omeprazole	0.5% MC	Gavage	Liver / Kidney	100	300	1000	100	300	1000	

Examples of a data base

Class: Toxicology

Term IRI: http://purl.obolibrary.org/obo/NCIT_C17206

Definition: Toxicology is the branch of pharmacology that deals with the nature and effects and treatments of poisons. [def-source: NCI]

Annotations

- **ALT_DEFINITION:**Toxicology is the study of the adverse effects of chemical, physical or biological agents on people, animals, and the environment.; The study of poisons, including the source, effect, and treatment of poisoning. It is a branch of pharmacology (the study of drugs).
- **Contributing_Source:**CDISC
- **Legacy_Concept_Name:**Toxicology
- **Preferred_Name:**Toxicology
- **Semantic_Type:**Biomedical Occupation or Discipline
- **UMLS_CUI:**C0040541
- **code:**C17206
- **has exact synonym:**toxicology; Toxicology; TOX
- **in subset:**CDISC SEND Terminology; CDISC SEND Study Category Terminology; Clinical Data Interchange Standards Consortium Terminology

Examples of data bases



INDICATORS ▾

DATABASES ▾

NBIC +

METHODOLOGY ▾



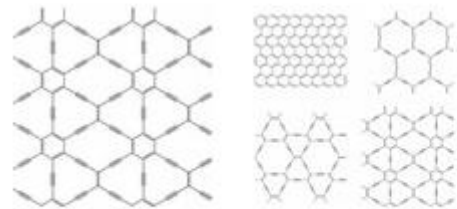
LOGIN

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43 NANOMATERIALS IN 1,844,645 ARTICLES, 220,026 PATENTS AND 3,272 PRODUCTS

GRAPHYNE

Article : 672 Patent : 21



FAIR data principle

To be Findable:

- F1. (meta)data are assigned a globally unique and eternally persistent identifier.
- F2. data are described with rich metadata.
- F3. (meta)data are registered or indexed in a searchable resource.
- F4. metadata specify the data identifier.

To be Accessible:

- A1 (meta)data are retrievable by their identifier using a standardized communications protocol.
 - A1.1 the protocol is open, free, and universally implementable.
 - A1.2 the protocol allows for an authentication and authorization procedure, where necessary.
- A2 metadata are accessible, even when the data are no longer available.

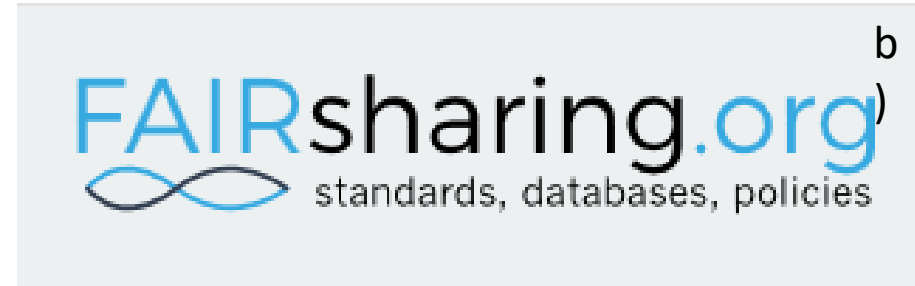
To be Interoperable:

- I1. (meta)data use a formal, accessible, shared, and broadly applicable language for knowledge representation.
- I2. (meta)data use vocabularies that follow FAIR principles.
- I3. (meta)data include qualified references to other (meta)data.

To be Re-usable:

- R1. meta(data) have a plurality of accurate and relevant attributes.
 - R1.1. (meta)data are released with a clear and accessible data usage license.
 - R1.2. (meta)data are associated with their provenance.
 - R1.3. (meta)data meet domain-relevant community standards.

Challenges



Problems to be solved:

a) data, information and knowledge is **siloes (isolated, separated)**

b) data, information and knowledge is human readable but **not machine readable**, not FAIR!

By Risk Governance Council:



Nano Risk Governance council

Nano Risk governace council (NRGC)

One of the main goals of three H2020 RIA risk-governace projects (NANORIGO, RiskGone, Gov4Nano) will establish a **science-based safety governance body for nanomaterials**, in the form of a transparent, self-sustained European Risk Governance Council (ERGC). The role of the ERGC is to provide expert opinions on the governance of engineered nanomaterials (ENMs).



NRGC for regulation

EU NANO REGULATION

DG GROWTH is EU commission **service**



DG GROWTH **supervises** certain regulatory agencies European Chemicals Agency
(ECHA)

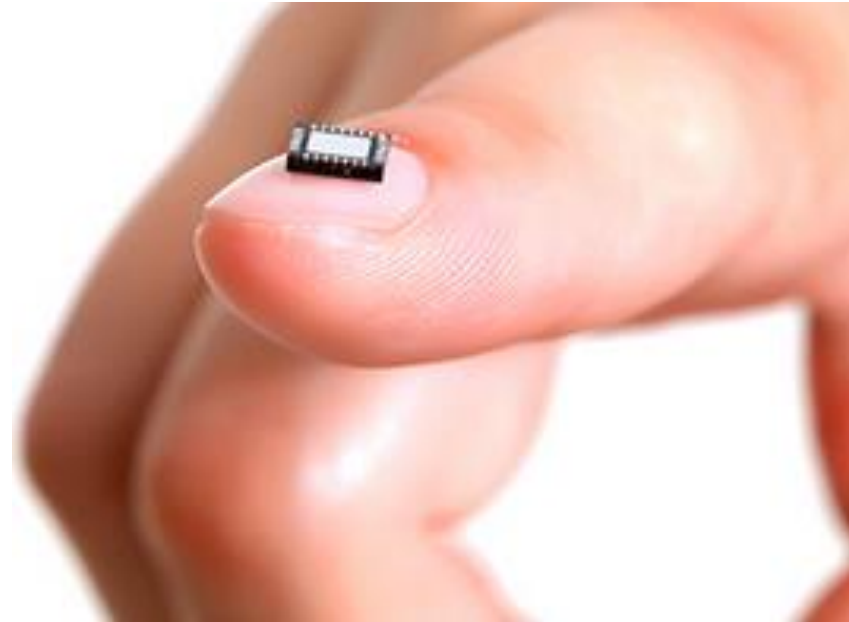


the European Chemicals Agency (ECHA) implements the EU's
legislation on **chemical products**



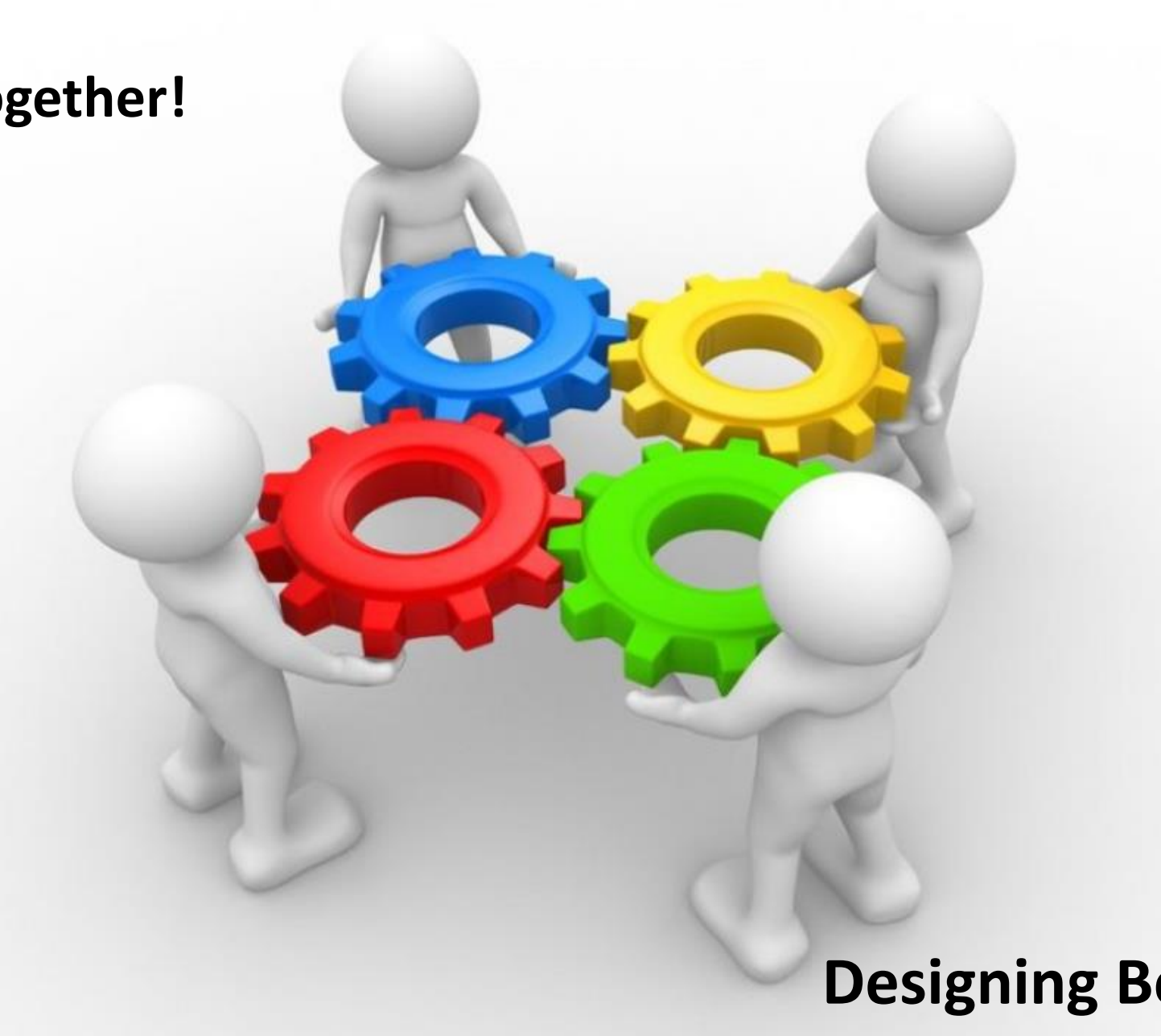
REACH and CLP are EU regulations

NRGC for nanoinnovation



Safe **NANO** Innovations

Working together!



Designing Better, Together!



NANORIGO European Union's Horizon 2020
research and innovation programme
grant agreement No 814530



Thank you for your attention!



REPUBLIKA SLOVENIJA
MINISTRSTVO ZA GOSPODARSKI
RAZVOJ IN TEHNOLOGIJO



EVROPSKA UNIJA
EVROPSKI SKLAD ZA
REGIONALNI RAZVOJ
NALOŽBA V VAŠO PRIHODNOST



SRIP
ZDRAVJE
MEDICINA

Slovensko inovacijsko stičišče
SIS EGIZ

